

## Bulgarian pharmaceutical market overview – August 2005

### Summary

#### A. MARKET HIGHLIGHTS AND BEST PROSPECTS

##### 1. Market Profile

Over the past 4 years the Bulgarian pharmaceutical market is characterized by a continuous trend towards increase of imported vs. domestic products. The growth of the Bulgarian pharmaceutical market for 2004 is 15-20% over 2003 mainly due to sales of more expensive products, higher sales to hospital market and rising OTC sales volume. The reasons behind this trend are the intensive advertising of OTC products, higher spending of households for medicinal products, increased share of public financing, further growth of several domestic producers such as Aktavis (former Balkanpharma), Sopharma, Chaikapharma and Biovet, further growth of the sales force of several importers and wholesalers, introduction of VAT on pharmaceutical products and increased prices. The ratio 2/1 in favor of pharmaceutical imports vs. domestic production (which will remain generic oriented) is due mainly to the higher prices of the life-saving and life-supporting drugs.

In general the total pharmaceutical market accounted to Euro 280-300 million in 2002, Euro 340 million in 2003 and Euro 350-365 million in 2004 at CIP/EXW prices.

In terms of retail prices the Bulgarian pharmaceutical market reached Euro 631.5 million (pharmacies plus hospital sales) which is an increase of close to 20% over 2003.

The distribution of pharmacy vs. hospital sales is 80% vs.20% whereby the hospital sales growth is 8.5% whereas the pharmacy sales have increased by nearly 20%.

Beginning of 2004 the Government of Bulgaria i.e. Ministry of Healthcare introduced the so-called Positive Drug List (PDL) while the National Health Insurance Fund issues a Reimbursement List. The PDL consists of products, grouped under their anatomical-therapeutic-chemical (ATC) code. These products cover socially important and recognized groups of diseases and are selected on the basis of efficacy, safety and pharmacoeconomic indicators. The PDL Committee with the Ministry of Health rejected applications only for products that have much cheaper sufficiently good alternatives. It claims to be covering all major diseases of social significance such as oncology, cardiovascular diseases, neurology, psychiatry, metabolic disorders, allergies and respiratory diseases.

The PDL and all corresponding specific regulations channeling drug reimbursement were meant to decrease the share of original, innovative products whenever generics are available and to guarantee their reimbursement by the public funds.

The total number of products included in the PDL for 2005 is 2,813 trade names and 771 international non-proprietary names (INNs) against 2,477 trade names and 667 INNs in 2004. The PDL gives both the INNs and the trade names by dosage forms. All drugs with identical INN are considered to be equally effective. The difference remains in the price. Comparison of the cost effectiveness is carried between drugs with different active substances. Thus there are two major lists of drugs comprising the PDL:

- Listing in Part A is by international non-proprietary names (INN) only plus dosage form and strength with pharmacotherapeutic and cost advantages over competitors and
- Part B includes all multisource brands containing Part A active ingredients  
Along with marketing authorization holders

A pharmaceutical product can be included in the National Health Insurance Fund (NHIF) reimbursement list only after it is listed in the PDL.

In 2003 and 2004 the Bulgarian Ministry of Health and Parliament endorsed the Data Exclusivity clause and the Roche-Bolar amendment to the existing Law on Healthcare. This translates into recognition of a 20-year patent protection term for the pharmaceutical products. Supplementary protection certificates (SPC) are envisaged by the date of accession. In 2003 the government introduced a six-year data exclusivity whereby for high-tech and bio products its validity covers 10 years. Parallel to that, a Roche-Bolar clause was endorsed thus allowing testing and regulatory activity to be initiated two years before the patent expires.

Outpatient care is partially funded by the NHIF through 28 regional health insurance funds and 121 municipal offices. On the other hand the NHIF covers just one fifth of hospital expenditures through 120 clinical paths and the balance is funded by the Ministry of Health and the local authorities. A serious issue is that the structure of hospital services and medication cost is done incorrectly and hospitals often pay much more than the foreseen NHIF subsidy.

The hospital market is still underfinanced and very badly supplied with drugs and medical equipment. It often suffers simple consumables shortage. In many cases even patients are encouraged to contribute by bringing in food, medication and/or make donations. The hospital market accounts for about 20% of the total drug sales. It is financed by the Ministry of Health, by Municipalities and NHIF through budget subsidies on the basis of the so-called "clinical paths" For less than two years the number of clinical paths increased from 80 to 130 while financing remains the same.

The OTC market varies by value in the range between 12-18% and by volume approx. 34% of the overall pharmaceutical market.  
OTC products have been released from price controls in 2004.

A lot of distribution marketing changes are expected to happen with the market entry of the first international pharmaceutical trader and wholesaler Phoenix Group of Germany like marketing the OTC products outside the drug stores, enforcement of e-commerce with pharmaceutical products, introduction of non-traditional medicinal products and food supplements and full compliance with Good Distribution Practice (GDP) and ISO 9001:2000 standards. It is likely that Phoenix will lobby for marketing the OTC products outside the drug stores and endorsement of e-commerce with pharmaceutical products.

There are approximately 30 domestic pharmaceutical manufacturers, 330 wholesalers who import and market pharmaceutical products for over 4500 pharmacies around Bulgaria and less than a dozen distributors which hold approximately 90 % of the domestic pharmaceutical market.

## 2. Statistical data

There are three main sources that officially publicize information on drug sales in Bulgaria. The Ministry of Healthcare is one of them. It publishes information on direct financing for expensive drugs and under special programs. The National Health Insurance Fund (NHIF) is the second source. It reports financing of drugs through the so-called clinical paths in hospitals and yet the share of the drug therapy remains unknown. And the third source is the Bulgarian Drug Agency (BDA) which issues the sales authorizations for every batch.

The overall pharmaceutical market for 2002 accounted to Euro 280-300 million, Euro 340 million in 2003 and Euro 350-365 million in 2004 at CIP/EXW prices.

In terms of retail prices the Bulgarian pharmaceutical market reached Euro 631.5 million (pharmacies plus hospital sales) which is an increase of close to 20% over 2004.

This is a very rough estimate though and it incorporates little amount of parallel/illegal imports.

The dynamics of the NHIF disbursement for outpatient drugs is as follows:

Year	2000	2001	2002	2003	2004	2005
Reimbursement in Euro	34.870	93.198	122.207	126.545	120.921	Budget estimate – 125.27

The public expenses for healthcare in general are specified in the table below. The ROE applied is \$1=BGN 1.6

In \$ million			
	2003	2004	2005
GDP	21,506.38	23,801.25	25,896.25
GDP per capita	2,757.25	3,051.25	3,312.50
Public expenditures for healthcare	887.50	879.38	1,180.63
As % from the GDP for healthcare	4.0%	4.3%	4.3%
Per capita	110.0	130.63	141.88
Public expenditures for pharmaceutical products	354.38	361.88	369.5
As % from the public expenditures for healthcare	39%	41%	31%
Public expenditures for pharmaceutical products per capita	43.13	53.75	43.75

### 3. Best Sales Prospects

Best sales prospects include pharmaceutical products for treatment of socially recognized diseases such as diabete, oncology, cardiovascular diseases, neurology, psychiatry, metabolic disorders, allergies and respiratory diseases.

## B. COMPETITIVE ANALYSIS

### 1. Domestic production

There are a total of 13 main pharmaceutical manufacturers in Bulgaria: Aktavis (with its three subsidiaries), Biovet, Sopharma, Unifarm, NIHFI, Chaikapharma, BU-Bio, National Center for Haemathology & Transfusiology, Inbiotech, Biomeda and Vet Prom.

The major domestic drug manufacturers emerged from the former Bulgarian pharmaceutical companies Balkanpharma, Sopharma and Biovet after their privatization and restructuring. Typical feature of the Bulgarian pharmaceutical production leaders is production of generics to for the domestic, Russian, Polish, Ukrainian, Latin American and Asian markets. Although figures vary from year to year, domestic production normally accounts for about 30% to 40% of the domestic sales in value and for about 65% to 75% in number of packages.

Actavis, the new corporate identity of former Iceland Pharmaco Group and the owner of former Balkanpharma, exports almost 75% of its production. It has approximately 12% share of the domestic pharmaceutical market. The company has three subsidiaries all over Bulgaria – in the cities of Troyan, Doupnitsa and Razgrad. It manufactures approx 10 products under license of Hoffman LaRoche, Aventis, Merck and Ethypharm.

Sopharma is engaged in research, manufacturing and trade in proprietary pharmaceutical substances, phytochemical products and finished drug forms. It also manufactures products under license of leading research-based companies such as GSK and Boehringer Ingelheim. It is unique for the country with its ampoule production. It has less than 10 % market share of the domestic pharmaceutical market of which 35 % is for galenic products. Major shareholders in Sopharma are Electroimpex AD (60%) and Unifarm Holding (40%).

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Biovet holds a 25% market share of the domestic vet pharmaceutical market and 95% of its products are exported. It produces veterinary products, enzymes, enzyme complexes and probiotics for application in the foodprocessing and forage industry. Company is aggressively expanding. Its last acquisition target is the Dutch Intervet International B.V, subsidiary of Akzo Nobel International for antibiotics, vaccines and veterinary/human medicine supplements. It is negotiating procurement of the Aktavis subsidiary for veterinary supplements in Macedonia as well as part of parent company shares in Bulgaria.

Chaikapharma was established and licensed in 2000 for primary packaging of tablets and blisters, secondary packaging in carton packages and boxes and labeling of sealed ampullas. In 2001 it passed GMP audit by Hoffman LaRoche for primary and secondary packaging of two of its products.

Unifarm is the largest manufacturer of acetate and the only manufacturer of bicarbonate solvents for haemodialysis in Bulgaria (covering almost 60% of the demand).

Full GMP compliance for the domestic drug manufacturers came into force in April 2003. Some companies such as Balkanpharma (now Actavis) and Medica-Sandanski built new greenfield facilities to meet the regulations. Others, such as Sopharma and Biomeda made extensive upgrade and restructuring of their facilities. Others – Chaikapharma are expected to meet the GMP requirements too.

There is only one manufacturer of vaccines in Bulgaria – the National Center for Infectious and Parasitic Diseases with a very modest market share.

## 2. Third country imports

Third country imports can be divided into three main groups – generic, original products under patent protection and OTC importers.

Hungarian, Slovenian, Polish and German companies are among the majority generic-product importers.

The original-under-patent-product importers are sound names such as Astra Zeneka, Bayer, Berlin-Chemie, Boehringer Ingelheim Pharma, Fournier Laboratories, Les Laboratoires Servier, Lundbeck, Novartis, Novo Nordisk, Roche, Sanofi, Solvay Pharma and Yamanouchi Europe. Their market share is estimated at approx 52-59%%

Finished pharmaceutical products are produced from predominantly imported chemicals (active ingredients and substances) coming from India, China and the European Union. Actavis and Sopharma then export a large share of their finished product to other markets

Roughly 36-38% of the finished product is then exported to other markets.

### 3. U.S. market position and share

The US pharmaceutical companies represented on the Bulgaria market are: Pfizer, MSD, Bristol Myers, Glaxo, Eli Lilly, Genzyme, Abbot, Janssen-Cilag, Shering Plough USA, 3M. US pharmaceutical companies enjoy good reputation and market share of 21% (at manufacturers' price sales volumes) in 2003 and 24% in 2004.

### C. END-USER ANALYSIS

The number of active players on the Bulgaria pharmaceutical market in 2004 was 323 companies of which 76 (19 of which being the largest ones) companies have authorizations to produce locally.

Per the existing legislation the pharmaceutical manufacturers can market directly their products only through authorized distributors/dealers. They can participate in government procurement tenders organized by the Ministry of Health (MoH), NHIF and hospitals only through their authorized distributors/dealers – the wholesalers.

The total number of importers/wholesalers on Bulgarian Market varies around 350. At the end of 2004 the total number on the Bulgarian market was approximately 330. Under a change in the Regulation on Wholesale of Drugs in 2004 the licenses are no longer divided into partial and full and are issued by the Minister of MoH upon coordination with the Bulgarian Drug Agency. Locally based (Bulgarian) pharmaceutical manufacturers are entitled to distribute their own products, based on the manufacturing license that they have. They can participate in the government procurement tenders organized by MoH, NHIF and hospitals directly. Foreign manufacturers are represented in Bulgaria in two ways:

- By representative offices, which are not legal entities and as such are not eligible to conduct commercial activities. They perform only promotion and marketing. The sales of drugs are done directly from the foreign legal entity to an authorized dealer who then distributes and sells the drugs to pharmacies and participates in tenders.
- By local subsidiaries (legal entities), which are owned by the foreign company and have a drug distribution license per the Bulgarian legislation. They participate in MoH and NHIF tenders directly, and legally can sell to pharmacies, although they don't because they do not have their distribution network. Due to the same reason, they authorize local wholesalers for hospital tenders.

Recently more and more foreign pharmaceutical companies are establishing local subsidiaries, licensed as wholesalers under the Bulgarian law.

The licenses are issued by the MoH upon coordination with the Bulgarian Drug Agency.

More than 100 international pharmaceutical companies have representation offices in Bulgaria. 23 of them are members of the Association of Research-Based Companies. Majority are members of the Association of Foreign Pharmaceutical Manufacturers in Bulgaria. The US pharmaceutical companies are also members of the PhRMA Bulgaria group and the American Chamber of Commerce.

Main customer for all of them remains the government through the NHIF outpatient drug policy, 21 university hospitals, 28 multifunctional hospitals (through subsidies), dispensaries and 64 haemodialysis centers. NHIF reimburses entirely or partially 1500 medicinal products for approx \$163 million) while hospitals cover an approx. amount of \$38 million). NHIF reimburses entirely or partially 850 medicinal products for approx \$163 million while hospitals cover an approx. amount of \$38 million). Priority reimbursable groups of diseases are: cardiovascular, neuro, gastroenterological, diabetes, sclerosis, multiple sclerosis and metabolic disorders.

#### D. MARKET ACCESS

##### 1. Import Climate

The import of pharmaceutical products is performed and controlled by:

- The Ministry of Health based on the new Health Act enforced in January 2005 that replaced the 30 year old Law for Public Health. The full text of the Law is published in State Gazette #70/2004
- The Ministry of Health through the Positive Drug List (PDL)
- The National Health Insurance Fund through the Reimbursement List (RL)
- Approximately 50 regulations which are in the process of redrafting and or amendment to comply with the new Law and EU standards
- The Bulgarian Drug Agency which controls registration of batches and issues import authorizations and marketing authorizations
- The State Agency Customs and
- The Ministry of Finance tax authorities

In 2003 and 2004 the Bulgarian Ministry of Health and Parliament endorsed the Data Exclusivity clause and the Roche-Bolar amendment to the existing Law on Healthcare. This translates into recognition of a 20-year patent protection term for the pharmaceutical products. Supplementary protection certificates (SPC) are envisaged by the date of accession. In 2003 the government introduced a six-year data exclusivity whereby for high-tech and bio products its validity covers 10 years. Parallel to that, a Roche-Bolar clause was endorsed thus allowing testing and regulatory activity to be initiated two years before the patent expires.

Pricing of the prescription pharmaceutical products in general and the ones included in the PDL is based on the reference prices of these products in 9 countries – Romania, Hungary, Poland, Czech Republic, Slovenia, Spain, Portugal and Austria.

Pricing and reimbursement level of the pharmaceutical products included in the NHIF reimbursement list is again based on the average prices from 8 countries, multiplied by a certain percentage applied for different groups of drugs. The reference countries are Czech Republic, Poland, Hungary, Romania, Slovakia, Greece, Latvia and Slovenia.

The rule applied is that the prices of these products should not be higher than the lowest price among the reference countries.

Prices of the OTC products have to be registered by the MoH. This is a simple notification regime.

## 2. Distribution/Business Practices

### 2.1. Wholesale drug distribution

2004 was a turning point for the distribution market of pharmaceutical products in Bulgaria when 3 of the large wholesalers declared insolvency (Magined, Pharmexpress and Babylon-L) and several others restructured through obtaining shares in other large wholesalers (the majority shareholder in Sopharma – Elpharma acquired shares in Global Medical Kaliman and Sanita). The market niche that emerged from these events was immediately filled in by other market players. In the hospital supplies segment these were the Commercial League, Higia, Almus Pharma, Nikpharma 2004, Pharmapro, Propharmazia, MC Pharma, Alfa Pharmaceutical and Chimimport Pharma.

Champions of community pharmacies became Higia, Libra and Sting. Recently Higia emerged as one of the companies with strong position in public tendering thus expanding its former traditional services provided to the free pharmacy market. The fourth company that joined the Higia, Libra and Sting trio in supplying products to independent pharmacies is Biomeda.

The first involvement of an international trader and wholesaler of pharmaceutical products on the Bulgarian market is registered in June 2005. The 60% German investor owned Libra AG announced its merger with the Phoenix Group of Germany.

### 2.2. Retail drug distribution

The Drug Act explicitly forbids the sales of any type of pharmaceuticals in other outlets such as general stores. Electronic sales are also forbidden. Drugstores are specific categories of shops for health related items and OTC products. They cannot influence the market because the products sold in them are specified in a list approved by the Ministry of Health. The pharmacy network is overdeveloped to a point where often a dozen of pharmacies exist in an area of a few hundred meters. The overall number of pharmacies in Bulgaria is 4518 compared to 4000 in 2003. This number reaches its capacity limit due to the fact that a certified pharmacist (totally 5000 in Bulgaria at present) can manage only one pharmacy.

25 to 30% of the retail distribution of pharmaceutical products is channeled through the network of pharmacies, the largest ones being Sanita Franchise (60 around Bulgaria), Seiba (110), Sofiiski apteki (56) and Obratzsovi apteki (170).

## 3. Financing

The two main sources for financing of pharmaceutical products purchases are central government funding (Ministry of Health and NHIF budgets) and local government funding through the budget of municipalities.

Central and regional budgets cover premiums for the poor, unemployed, retired, children and the armed forces.

4.3% of the GDP i.e. approximately \$ 1,107.9 million (at the exchange rate USD 1=BGN 1.60) are allocated for healthcare of which about 30 % (reimbursement, public financing programs) are spent for pharmaceutical products.

The budget for life-saving drugs for 2005 is 20% higher than the budget for 2004 and it amounts to \$56.3 million.

## 4. Important web sites

Ministry of Health – [www.moh.government.bg](http://www.moh.government.bg)  
Bulgarian Drug Agency – [www.bda.bg](http://www.bda.bg)  
National Health Insurance Fund – [www.nhif.bg](http://www.nhif.bg)  
Ministry of Economy – [www.mi.government.bg](http://www.mi.government.bg)  
American Chamber of Commerce – [www.amcham.bg](http://www.amcham.bg)  
Executive Agency Customs – [www.customs.bg](http://www.customs.bg)  
Association of Research-Based Pharmaceutical Manufacturers in Bulgaria – [www.arpharm.org](http://www.arpharm.org)  
PhRMA Bulgaria – [www.amcham.bg](http://www.amcham.bg)  
Top Management Advisors – [www.pharma-bulgaria.com](http://www.pharma-bulgaria.com)  
Bulgarian Pharmaceutical Group – [www.bpg.com](http://www.bpg.com)  
IMS Health Bulgaria – [www.imshealth.com](http://www.imshealth.com)  
Magazine Pharmacist – [www.pharmacist-journal.com](http://www.pharmacist-journal.com)  
Bulgarian Pharma Union – [www.pharma-union-bulgaria.com](http://www.pharma-union-bulgaria.com)

#### 4. Trade Promotion Opportunities

There are two major international trade shows organized in Bulgaria which are dedicated to healthcare and more specifically to pharmaceutical products.

##### 4.1. Bulmedica, Buldental, Buloptics, Bullabor

Organizer: Bulgarreklama  
[www.bulgarreklama.com](http://www.bulgarreklama.com)

##### 4.2. Medicus, Dento, Galenia

Organizer: Plovdiv Fair  
[www.fair-plovdiv.com](http://www.fair-plovdiv.com)

For more information or market entry solutions please contact:

Uliana Kanelli  
U.S. Commercial Section  
U.S. Embassy Sofia  
Tel: + 359-2-937-5100  
Fax: + 359-2-939-5735  
E-mail: [Uliana.Kanelli@mail.doc.gov](mailto:Uliana.Kanelli@mail.doc.gov)